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Технические характеристики на паровоздушные стерилизаторы GEV, водяные каскадные стерилизаторы GEC, паровые стерилизаторы GSS Р для фармацевтических препаратов компании **GETINGE**

The next generation of efficiency

GSS P Series Steam Sterilizers for Biopharma

GSS P Series Steam Sterilizers help you improve efficiency and process flow. We work together with you every step of the way to give you the solution you need and can trust.

Your product is our priority

Setting a new standard

Reliable contamination prevention is essential in biopharmaceutical production. GSS P Series Steam Sterilizers help ensure product quality and a safe work environment, while making it easier for you to achieve high performance, maximum productivity and a streamlined process.

Getinge has a long history as a partner in the biopharmaceutical industry. By being part of your production, we can contribute to manufacturing cures that help improve people's health and save lives.

Wherever you are in the world, we deliver on stringent local requirements and regulations. You can count on dedicated support from planning, through full production to aftersales service.

Based on years of engineering excellence, the GSS P Series is a refined product combining design and innovation with a comprehensive approach to safe component and equipment processing.

Your production flow is our priority. The GSS P Series sets a new standard for steam sterilizers in your biopharmaceutical production.

With the GSS P Series as a foundation, a modular, flexible solution is designed to fit your production and improve efficiency.



Reliable

State-of-the-art design, secure process configuration, an intuitive interface and global service network are all part of the reason why the GSS P Series helps you eliminate unplanned production stops.



Safe

It is vital to protect both product integrity and staff in biopharmaceutical production. The GSS P Series is designed to optimize a safe work environment and ensure product quality.



Flexible

Every biopharmaceutical production facility and country has its own specific regulations and requirements. The GSS P is a flexible solution and can be customized to meet your production needs.

Quality without compromise

The GSS P Series is our latest steam sterilizer built on experience and customer insights. It is optimized to meet the core functionality and flexibility needed in a modern biopharmaceutical production environment.

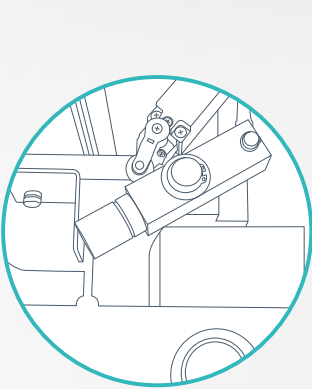
The GSS P is engineered with high-quality components to enhance contamination control, secure a safe process, promote best practices and deliver reliable outcomes and high throughput. Construction and design from sanitary stainless steel surfaces to enhanced ergonomic interfaces, are carefully integrated into a high performing solution critical to quality assurance.

GSS P is designed for easy use and integration in any biopharmaceutical production flow.

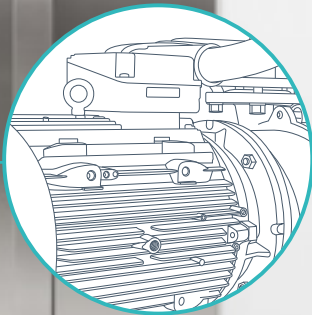
It is engineered to reduce your eco-footprint, optimizing energy and water use with efficient insulation and minimal mass of pressure vessel.

The GSS P can swiftly be put into operation thanks to the advanced Quality Process Management System that secures ease of validation and compliance to the intent of the Good Automation System (GAMP5) and ensures fulfillment of global and local regulations.

Ergonomic automatic doors for safety and convenience.



User-friendly display and intuitive HMI for quick, easy use.



High performance liquid ring vacuum pumps for optimal air removal and short process time.

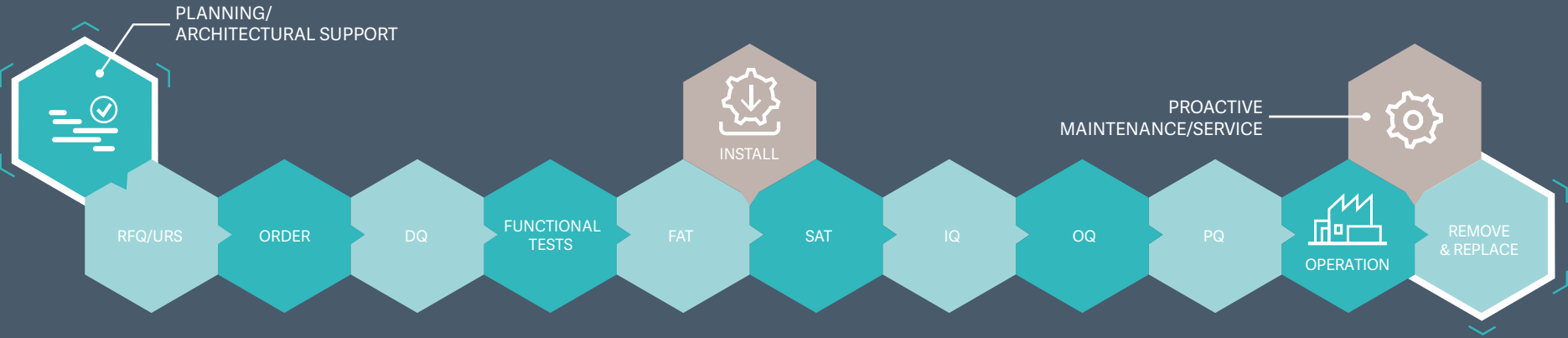
Sanitary stainless steel components are the foundation of reliable piping systems.



With you every step of the way

Our commitment goes far beyond supplying equipment. We support you with project planning and setting the right specifications and requirements.

Our experience in manufacturing, installation and commissioning allows us to manage the project from start to finish. When in operation, proactive maintenance secures your uptime. In short – we are with you every step of the way.



Examples of core features:

- Program combination adapted for biopharma applications
- Intuitive and user-friendly HMI
- User and password management
- GAMP5 project execution
- GMP design and documentation
- Uniform temperature distribution and accurate process control
- Air removal by highly efficient liquid ring vacuum pump
- ECO-system, recirculation of vacuum pump sealing water
- Diaphragm sealed instruments in process system
- Sanitary stainless steel process piping
- Stainless steel chamber construction
- Robot welded and highly polished chamber
- Ergonomic and safe machine handling

Technical data

MODEL	USABLE DIMENSIONS (mm)	USABLE DIMENSIONS (INCH)	CHAMBER VOLUME (Nominal)	
	W x H x D	W x H x D	LITRES	FEET ³
GSS 6710	660 x	26” x 26 ½” x 39 3/8”	470	16.0
GSS 6713	660 x	26” x 26 ½” x 51 1/4”	612	20.7
GSS 6910	660 x	26” x 36 ¼” x 39 3/8”	618	21.8
GSS 6913	660 x	26” x 36 ¼” x 53 1/8"	835	29.5
GSS 6915	660 x	26” x 36 ¼” x 60 5/8"	952	33.6
GSS 6917	660 x	26” x 36 ¼” x 66 7/8"	1051	37.1
GSS 71413	670 x	26 3/8” x 57 1/8” x 53 1/8”	1370	48.4
GSS 91413	870 x	34 ¼” x 57 1/8” x 53 1/8”	1762	62.2
GSS 91415	870 x	34 ¼” x 57 1/8” x 60 5/8”	2010	71.0
GSS 91418	870 x	34 ¼” x 57 1/8” x 70 7/8”	2349	83.0
GSS 91422	870 x	34 ¼” x 57 1/8” x 7’ - 2 5/8”	2871	101.4
GSS 91815	920 x	36 ¼” x 70 7/8” x 60 5/8”	2633	93.0
GSS 91825	870 x	34 ¼” x 70 7/8” x 8’ - 2 3/8”	4275	151
GSS 121422	1220 x 1450 x 2200 mm	48” x 57 1/8” x 7’ - 2 5/8”	3988	141

MODEL	USABLE DIMENSIONS (mm)	USABLE DIMENSIONS (INCH)	CHAMBER VOLUME (Nominal)	
	W x H x D	W x H x D	LITRES	FEET ³
GSS 92222	870 x	34 ¼” x 7’ - 2 5/8” x 7’ - 2 5/8”	4356	154
GSS 122222	1220 x 2200 x 2200 mm	48” x 7’ - 2 5/8” x 7’ - 2 5/8”	6050	214
GSS 182222	1800 x 2200 x 2200 mm	70 7/8” x 7’ - 2 5/8” x 7’ - 2 5/8”	8857	313

Designed for flexibility

GSS P Steam Sterilizers come in a range of 17 different chamber sizes with a flexible set of options and customization possibilities.

With a standard GSS P range for core functionality – and usable chamber capacities ranging from 10 to 400 ft³/ 0.4 to 9 m³ – the built-in flexibility of the GSS P allows for customization. Working closely together with you, we design a contamination prevention solution that suits your specific needs.

Examples of configuration options:

- Single-door or double-door, pass-through models
- Floor or pit-mounted
- Right or left side service access
- Cross contamination barrier (CCB) for integration in building
- Door interlock to prevent cross contamination for barrier pass through models
- Integral steam generator options
- In-situ filter integrity test (WIT)
- Process for liquids in open or closed containers
- Jacket cooling with water recirculation
- Network connectivity/SCADA
- Data integrity/21CFR Part 11
- Printer for batch reports
- Loading equipment: trolleys, shelves and racks



GEV Steam/Air Mixture Sterilizers

Rapid and versatile terminal sterilization for packaged pharmaceuticals

Getinge GEV sterilizers are designed for sterilizing pharmaceutical products that must be dry and ready for further handling immediately after the cooling phase.



Safe, efficient and cGMP
compliant terminal sterilization
processes



- Flexible process design
- Effective process control
- Efficient throughput
- Automated loading solutions

Optimizing process design

The correct packaging and drug delivery systems play an important role in easing drug administration and improving patient safety. Yet the wide variety of products and packaging styles present significant challenges for the biopharmaceutical industry. Terminal sterilization puts stringent demands on efficient sterilization while protecting both product and packaging.

Getinge supports you by defining optimal process parameters for your specific product and packaging. GEV Steam/Air mixture sterilizers offer versatile sterilization processes to achieve correct temperature and pressure throughout the process cycle.

Control over temperature and pressure

Temperature and pressure within the chamber must be carefully controlled and evenly distributed to prevent packaging deformation during sterilization.

Getinge GEV Steam/Air Mixture Sterilizers use sterile compressed air to apply support pressure to balance the environment with the internal load pressure, meeting each load's requirements for heating and cooling rates. Pressure and temperature sensors within the chamber control and adjust when necessary. A fan and ducting create a circulation pattern and maintain a homogeneous environment when it comes to temperature and pressure.



Automated loading solutions

In a busy production environment, transporting products to and from a sterilization chamber is a logistical challenge. Often large, heavy loads are moved daily to maintain productivity. Yet manual handling is difficult to control according to the validated processes. Getinge supports you with automated, ergonomically friendly solutions for load handling. Conveyor systems and robotic loading play an integral part in maximizing throughput and ensuring process control.

Rack design supports efficacy

Rack and shelf design play a key role in process efficacy and product protection. They must allow adequate and uniform flow of sterilizing media while supporting the product to prevent damage or deformation. Getinge supports you with wide variety of shelving systems, and offers test and prototyping services to assist in the design of shelving for your specific process requirements.



Optimized throughput

Pre-heating for dry loads

While steam-heating is energy efficient, the resulting condensation can be problematic for downstream processing. The drying result can be improved by pre-heating with dry air. In this process, the circulating air is heated

prior to steam injection. When steam is injected, less energy is required to raise the load to sterilization temperature. Less steam means less condensate, resulting in a drier load.

Rapid cooling

Getinge uses bundled heat exchangers placed in the path of the circulating steam/air mix to rapidly and efficiently cool the sterilized goods. As the product temperature decreases, the pressure is reduced; this maintains balance with the

prevent compression or rupture of the container. As result, the products emerge sterile, cool, dry, and ready for further downstream processing.

Sterilizers for all capacity needs

The GEV Steam/Air Mixture Sterilizers offer a wide range of chamber sizes and configurations ranging from 0,36m³ to 16,3 m³ to meet your capacity needs. The range also offers single or

on either side of the chamber. The sterilizers can be mounted in a cabinet, recessed between two walls, or recessed in a wall with a surrounding cabinet.

GEC Water Cascade Sterilizers

High-throughput terminal sterilization

GEC Water Cascade Sterilizers are primarily intended for terminal sterilization of large volumes of liquids in sealed glass or plastic containers.

Safe, efficient and cGMP compliant terminal sterilization processes



- Flexible process design
- Effective process control
- Efficient throughput
- Automated loading solutions

Water Cascade sterilizers deliver sterility of the product in a rapid cycle, yet are gentle

GEC Water Cascade Sterilizers

High-throughput terminal sterilization

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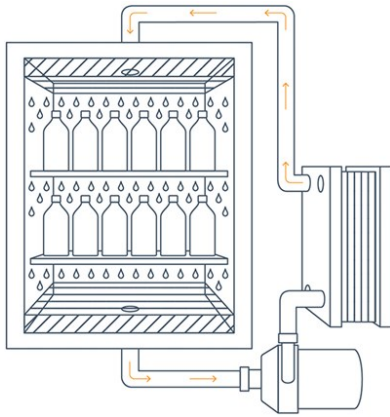
Flexible process design

Program and processing parameters play an important role in the and packaging. The GEC Water Cascade Sterilizers provide a versatile line-up of sterilization cycles to meet your products' unique requirements. Getinge works with you to define the correct processing conditions, and can conduct test runs on your products during evaluation to ensure optimal sterilization outcomes.



Automated loading solutions

In a busy production environment, **Accessories** to and from a sterilization chamber is a logistical challenge. Often large, heavy loads must be moved daily to maintain productivity. Yet manual handling is difficult to control according to the validated processes. Getinge supports you with automated, ergonomically friendly solutions for load handling. Conveyor systems and robotic loading play an integral part in maximizing throughput and ensuring process control.



Efficient throughput

Throughput is an important concern in production settings where large quantities of liquids in glass or plastic containers must be rapidly processed. GEC Water Cascade Sterilizers utilize a closed loop water system in combination with a high capacity pump that contribute to rapid heating and cooling and an overall short cycle time.

To meet various productivity needs, the GEC Water Cascade Sterilizers are offered in standard chamber sizes ranging from 0,43 m3 up to 16,2 m3. Getinge can support you with custom-made sizes and configurations to meet your specific production and



Effective process control

Correct pressure and evenly distributed temperature are key to process efficacy while preventing deformation or damage of containers. Temperature and pressure are determined by the liquid being sterilized, fill volume, container material style and type of closure.

During sterilization, water cascades from a perforated tray at the top of the chamber to create a uniform temperature throughout the load during the sterilization phase. Temperature and pressure are independently controlled; by accurately linking pressure

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